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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|------------------------|------------------------------------|------------------|
| 10/759,726 | 01/16/2004 | Raymond P. Warrell JR. | CELLTH 3.0-003 CONT | 8218 |
| 530 | 7590 | 11/24/2004 | CONT | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | EXAMINER PRYOR, ALTON NATHANIEL | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/759,726 | Applicant(s) WARRELL ET AL. | |
| | Examiner Alton N. Pryor | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

DETAILED ACTION

Applicant's arguments filed 9/1/04 have been fully considered but they are not persuasive. See arguments below.

I. Rejection of claims 1-21 under 35 USC 103(a) as being obvious over Zhang (US '011) or Yang (CN '908) or Chen (Blood, 1996, 88(3); pp. 105261) will be maintained for reason on record and reason as follows.

Applicant argues that Chen teaches a method of treating APL patients with 10 mg per day of ATO for 28-60 days. Applicant argues that Chen's treatment regimen is a flat dose amount rather than dosage according to body weight. Applicant agrees that instant invention is a kit with attached instructions for the administration of ATO to a patient with promyelocytic leukemia according to the patient's body weight. When examining the claims, Examiner is searching for the composition of the kit not the instruction as to how the kit is used. The composition of the instant kit consists of ATO, which is a well known chemical compound. Since ATO is well known in the art, it is obvious that it would have been packaged in some sought of container. The container in which the ATO is packaged can qualify as the kit. Note, in order for a kit with attached instructions to be patentable, the kit itself must to patentable without the attached instructions. New instructions to the use or application of an old kit or package comprising ATO is not patentable, since packages containing ATO are well known in the art. **Claim directed to kit for performing method of normalizing and amplifying ribonucleic acids was properly rejected as being obvious over the prior art, even though content of instructions in claimed kit differs from instructions in prior art, since addition of new set of instructions into known kit merely teaches new use for**

Art Unit: 1616

existing product, in that instructions do not interrelate with kit so as to produce new product, and since addition of printed matter to existing product will not distinguish invention from prior art in terms of patentability if printed matter is not functionally related to product.

Applicant argues that Zhang teaches a method of treating APL and AML by administering 1-10 mg ATO to patient in need thereof. Applicant argues that the actual dose administered to the patient in Zhang is a 10 mg flat dose of ATO rather than ATO administration by body weight as instantly claimed. Applicant acknowledges that Zhang teaches that smaller dosages should be administered to children. However, Applicant points out that Zhang does not provide an example of administering less than 10 mg of ATO to children. Examiner argues that the fact that Zhang discloses a range of ATO (1-10mg) and the administration of smaller doses of ATO to children suggests that ATO can be administered according to a subject's body weight. Examiner argues that Zhang is not required to show treatment regimen using all points in his disclose dose range of 1-10 mg of ATO. The fact that Zhang teaches a range of 1-10 mg of ATO suggests that dose amounts other than 10 mg can be administered to patients in need thereof. See argument above with respect to kit.

Applicant provides Ellison's Declaration to show that administration of ATO was done according to Body Surface Area (BSA) rather than according to body weight. Examiner refers to arguments above to illustrate that the prior art does suggest the administration of ATO according to body weight rather than according the BSA and / or flat dose amount. However, note that Ellison's declaration in this application is irrelevant since claims are directed to a kit rather than to a method of administration.

Art Unit: 1616

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

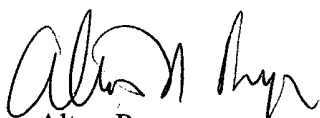
Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton Pryor', is written above the printed name.

Alton Pryor
Primary Examiner
AU 1616